IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ABBOTT CARDIOVASCULAR SYSTEMS, INC., and EVALVE, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 19-149-MN
EDWARDS LIFESCIENCES CORP., and EDWARDS LIFESCIENCES, LLC,	)	
Defendants.	)	

FIRST AMENDED COMPLAINT

Plaintiffs Abbott Cardiovascular Systems, Inc. ("ACS") and Evalve, Inc. ("Evalve") (collectively, "Abbott" or "Plaintiffs"), for their First Amended Complaint against Defendants Edwards Lifesciences Corp. ("Edwards Corp.") and Edwards Lifesciences LLC ("Edwards LLC") (collectively, "Edwards" or "Defendants"), allege as follows:

INTRODUCTION

1. Edwards has begun to willfully infringe multiple Abbott patents covering its MitraClip®, a medical device that is revolutionizing the treatment of a life-threatening heart problem.

2. Abbott spent years building a market from scratch for that patented product—over a decade from CE-mark approval in Europe, and two decades from the formation of Evalve. To

break into the market, Edwards tried to design around Abbott's patents. That effort failed due to "poor … results."[1]

3. Now, as Abbott's efforts to build a market expected to reach billions of dollars are paying off, Edwards has launched an infringing, copycat product called PASCAL that it is manufacturing in the U.S. The Court should preliminarily and permanently enjoin Edwards' infringement, which is undermining years of work and investment by Abbott.

4. Abbott's groundbreaking MitraClip treats mitral regurgitation ("MR"). MR is a life-threatening condition arising from the mitral valve failing to close properly, allowing blood to flow backwards in the heart. Before MitraClip, the standard of care for treating MR was highly-invasive open-heart surgery, requiring stopping a patient's heart. MitraClip avoided that high-risk surgery with an entirely new field of non-surgical treatment.

5. Abbott began developing MitraClip in the 1990s. Implanting a device into a beating heart presented enormous design, regulatory, doctor-training, and reimbursement challenges. Yet, Abbott persevered, overcoming all the hurdles associated with this first-in-class device. After years of demonstrated outcomes and study, Abbott is changing how the medical community thinks about its new non-surgical procedure known as "edge-to-edge repair."

6. MitraClip is so groundbreaking that the New York Times touted MitraClip in September 2018 *on its front page*, calling MitraClip a "huge advance" that "sharply reduced deaths

[1] Nocolo Piazza, et al., *Transcatheter Mitral and Pulmonary Valve Therapy*, J. AM. COLLEGE OF CARDIOLOGY. 53(20):1837-1851 at 1838-41 (2009); *see also* Michael J. Mack, *Percutaneous treatment of mitral regurgitation: So near, yet so far!*, J. of THORACIC AND CARDIOVASCULAR SURGERY 135(3):238 (2008).

among patients with a grim prognosis."[2] Doctors describe MitraClip as "a game changer," permitting them to treat MR "in a way we never thought we could."[3]

7. Because MitraClip is so pioneering—in the FDA's words, "a first-in-class device representing a breakthrough technology"[4]— Abbott has invested hundreds of millions of dollars and devoted nearly two decades to developing MitraClip, obtaining regulatory approvals, and training doctors throughout the world.

8. Abbott's investments are bearing fruit. In September 2018, for instance, a large clinical trial established MitraClip as the "first therapy" to treat certain "high-risk patients" with "difficult-to-treat" MR.[5] The clinical results were so "profound" that when announced at a major medical conference, the audience reacted with "spontaneous, rare, mid-presentation applause" and "cheering," reflecting a "once-in-a-lifetime" medical "revelation."[6] MitraClip "knocked it out of the park."[7]

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[2] Gina Kolata, *Tiny Device is a 'Huge Advance' for Treatment of Serious Heart Failure*, THE NEW YORK TIMES (Sept. 23, 2018), *available at:* https://www.nytimes.com/2018/09/23/health/heart-failure-valve-repair-microclip.html (last visited: March 4, 2019).

[3] *Id.*

[4] Letter from Denise Hinton, Chief Scientist, FDA to Stephanie Philbin, Goodwin & Proctor LLP, Re: Citizen Petition for Due Diligence Determination of Patent Term Extension for MITRACLIP CDS; Docket Nos. FDA-2014-E-2358; FDA-2014-E-2359 (FDA RADM Chief Scientist Letter) at 7–8 (July 12, 2018) (denying petition).

[5] Gina Kolata, *Tiny Device is a 'Huge Advance' for Treatment of Serious Heart Failure*, THE NEW YORK TIMES (Sept. 23, 2018), *available at:* https://www.nytimes.com/2018/09/23/health/heart-failure-valve-repair-microclip.html (last visited: March 4, 2019).

[6] D.I. 12, Ex. 13 at 21–22.

[7] Gregg W. Stone, *COAPT: MitraClip reduces hospitalization mortality in HF, mitral regurgitation*, CARDIOLOGY TODAY'S INTERVENTION ARTICLE (Sept. 23, 2018).

9. PASCAL's continued sale will transform a highly complex market in numerous ways, all impossible to quantify. Edwards is already targeting MitraClip customers, and has told investors PASCAL is an "alternative" to MitraClip.[8]

10. MitraClip is purchased in bulk, and a PASCAL sale could convert an entire MitraClip hospital to PASCAL. PASCAL also will interfere, and already is interfering, with the customer relationships Abbott has been building to expand the MitraClip market as well as the market for its future structural heart products.

11. Abbott stands to lose an unquantifiable number of customers and sales, even beyond MitraClip.

12. The timing could not be worse. Edwards is manufacturing PASCAL in the U.S., and launched PASCAL in Europe in February 2019. That follows right on the heels of Abbott's "seminal" clinical trial, called "COAPT," that established that MitraClip is effective in treating certain MR patients who have little other option, and that is expected to "expand … MitraClip['s] market into the multibillion-dollar range."[9] Abbott stands to lose the benefit of years of investment.

13. MitraClip is poised to be the standard of care for MR patients. To get FDA approval, Edwards is testing PASCAL against MitraClip in a "noninferiority" trial, designed to

[8] Transcript, Edwards Lifesciences Corporation Presentation at Goldman Sachs 39th Annual Global Healthcare Conference at 13–14 (June 13, 2018).

[9] Aallison Gatlin, *Abbott Tops Bearish Odds In 'Landmark' Study Of Heart Device*, INVESTOR'S BUSINESS DAILY (Sept. 24, 2018).

show PASCAL is not inferior to MitraClip (as opposed to a superiority trial).[10] Edwards concedes Abbott's COAPT trial will serve "as the benchmark" for expanding the market.[11]

14. Further, Edwards already appears intent on implying PASCAL can treat patients MitraClip cannot, even though Edwards is only now beginning to test PASCAL head-to-head with MitraClip in a non-inferiority study.[12] Regardless of their truth, Edwards' suggestions will irreparably harm MitraClip's reputation.

15. This is a classic case warranting an injunction. Infringement of just one valid claim is sufficient for an injunction. Yet PASCAL infringes dozens of valid claims in five patents.

16. Edwards' infringement is willful. Edwards has been aware of Abbott's patents and PASCAL's infringement at least since this suit was commenced and Abbott filed its Motion for a Preliminary Injunction and supporting declarations and exhibits. Those filings explained in detail how PASCAL meets each and every limitation of dozens of claims in Abbott's patents. The Court then issued an Order stating "it appears that Abbott may be able to establish a case on the merits." (D.I. 63 at 3.) Despite its knowledge of PASCAL's infringement, and the harm its infringement causes, Edwards deliberately launched PASCAL in Europe and is continuing to commercially manufacture and sell it. Edwards' knowing infringement is willful, wanton and egregious.

[10] Transcript, Edwards Lifesciences Corporation FQ3 2018 Earnings Call at 11 (Oct. 23, 2018).

[11] Transcript, Edwards Lifesciences Corporation Analyst/Investor Day at 34 (Dec. 5, 2018).

[12] Transcript, Edwards Lifesciences Corporation FQ3 2018 Earnings Call at 11 (Oct. 23, 2018).

17. Abbott's irreparable harm is established in multiple ways, including that PASCAL's launch has unjustifiably created a "two-player market," "the existence" of which alone "may well serve as a substantial ground for granting an injunction."[13]

18. The public interest also would be served by protecting patent rights and the innovation they encourage, particularly here, where MitraClip can serve the market on its own as it has done for years.

19. Edwards' willful infringement is precisely what our patent system's exclusionary rights are designed to protect against. Abbott's patents give it the right to protect the market that its groundbreaking inventions made possible. Edwards' infringement should be stopped first through a preliminary injunction and then through a permanent injunction. Abbott also should be compensated for Edwards' past infringement, including through the award of damages for Abbott's lost profits, which should be further enhanced three-fold due to Edwards' willful, wanton and egregious conduct.

NATURE OF THE ACTION

20. The United States Patent and Trademark Office ("USPTO") awarded a robust patent portfolio that protects Abbott's inventions relating to the MitraClip, including United States Patent Nos. 7,288,097 ("the '097 patent"), 6,752,813 ("the '813 patent"), 7,563,267 ("the '267 patent"), 7,736,388 ("the '388 patent"), and 8,057,493 ("the '493 patent") (collectively, "the Patents-in-Suit").

21. This is an action for infringement of the Patents-in-Suit.

[13] *Robert Bosch LLC v. Pylon Mfg.*, 659 F.3d 1142, 1151 (Fed. Cir. 2011).

22. This action is based on the Patent Laws of the United States, 35 U.S.C. §§ 100, *et seq.*

THE PARTIES

23. Plaintiffs form part of the structural heart and vascular businesses of Abbott Laboratories, a broad-based healthcare company with a robust portfolio of innovative and life-saving cardiovascular and structural heart products, including stents, surgical valves and minimally invasive valve repair and replacement devices.

24. Plaintiff ACS is a corporation organized and existing under the laws of the State of California and has its principal place of business at 3200 Lakeside Drive, Santa Clara, California. ACS markets and sells the MitraClip under exclusive license to the Patents-in-Suit from Evalve.

25. Plaintiff Evalve is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 4045 Campbell Avenue, Menlo Park, California. Evalve holds legal title to the Patents-in-Suit as the assignee.

26. Edwards Corp. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at One Edwards Way, Irvine, California.

27. Edwards LLC is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at One Edwards Way, Irvine, California.

28. Edwards has manufactured, does manufacture, and will manufacture medical devices for cardiovascular procedures, including the PASCAL mitral valve repair system, in the United States for export, use, sale and offer for sale outside of the United States, including in Europe.

JURISDICTION AND VENUE

29. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) *et seq*.

30. This Court has personal jurisdiction over Edwards Corp. and Edwards LLC because, *inter alia*, they are incorporated in Delaware, and thus reside in this District.

31. Venue is proper in this District under 28 U.S.C. §§ 1391(a)–(c) and 1400(b), because, *inter alia*, Edwards Corp. and Edwards LLC are incorporated in Delaware, and thus reside in this District.

BACKGROUND

The Human Heart

32. The heart is vital to human health, pumping blood throughout the body, which supplies oxygen and nutrients to the body's organs and aids in the removal of carbon dioxide and other wastes. If disease or injury impairs the blood pumping ability of the heart, the body's organs may not receive adequate blood to function normally.

33. The human heart has four chambers. The heart's upper chambers are the "atria" and the lower chambers are the "ventricles." The upper chambers are further divided into the left atrium and right atrium, and the lower chambers into the left ventricle and right ventricle (from a patient's perspective of the heart):

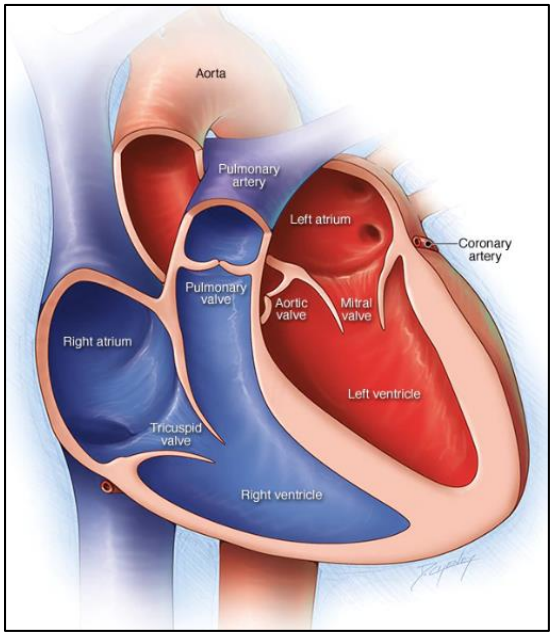

Figure 1
(https://www.mayoclinic.org/diseases-conditions/mitral-valve-regurgitation/symptoms-causes/syc-20350178)

34. The contraction and expansion of the atria and ventricles causes blood to be pumped throughout the body.

35. The heart has four one-way valves, each one positioned at the outflow portion of one of the chambers of the heart. The valves open and close in coordination with the pumping of the heart to unidirectionally control the flow of blood. Each valve has a set of leaflets that, in a healthy heart, open to allow blood to pass from a chamber, and close to prevent blood from flowing backwards into the chamber from which it came. In this way, a healthy heart supplies the organs of the body with oxygen and nutrients.

36. One of the four heart valves is the mitral valve. The mitral valve is located between the left atrium and the left ventricle:

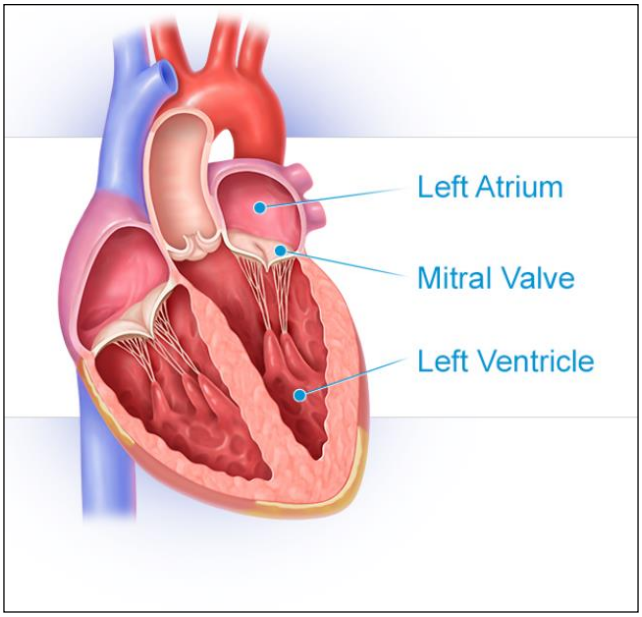

Figure 2
(*http://mitraclip.com/about_mitral_regurgitation*)

Mitral Regurgitation

37. Heart valves sometimes do not function properly, leading to a heart condition. One of these heart conditions is MR.

38. MR occurs due to abnormalities of the mitral valve. When the mitral valve does not close properly during contraction of the left ventricle, blood can flow backwards through the mitral valve and back into the left atrium. This can result in irreversible damage to the cardiac functions of the heart as well as several other serious health complications.

Prior Surgical Treatments for MR

39. Historically, MR was treated with open-heart surgery in which the heart is exposed by way of a large opening cut through the chest and stopped, the patient put on a cardiopulmonary bypass machine, and the valve either replaced or repaired.

40. One method of open-heart surgical repair for MR, put into practice by Dr. Ottavio Alfieri in the early 1990s, involved suturing the mitral valve leaflets to each other to create a double-orifice in a technique that became known as the "Alfieri" stitch:

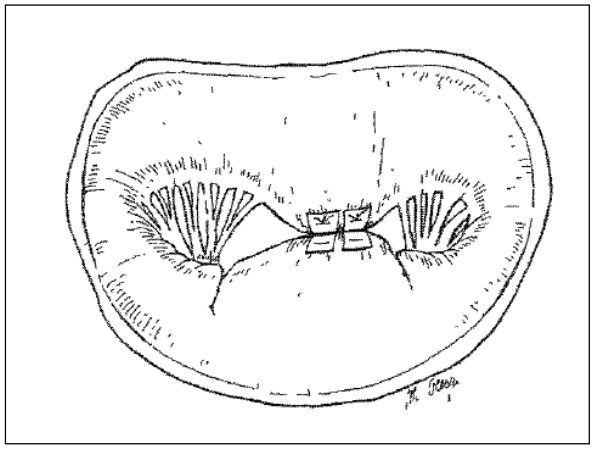

Figure 3
***(C. Fucci et al., "Improved results with mitral valve repair using new surgical techniques, Eur. J. Cardio-thorac. Surg.* Vol. 9, No. 11 p: 621–627 at 623, Fig. 2 (1995))**

41. Open-heart surgery for MR is associated with some significant disadvantages, including significant medical risks and severe surgical trauma.

42. An open-heart surgery patient will often require several months of recovery.

43. Open-heart surgery, and its associated recovery time, can be costly for patients and health care providers.

44. Some patients, due to their advanced age or medical conditions, cannot undergo open-heart surgery.

45. Thus, before the development of MitraClip and the inventions of the Patents-in-Suit, there remained a large unmet need for an effective, less invasive medical treatment for patients suffering from MR.

Abbott's MR Solution: MitraClip

46. Applying their expertise and ingenuity as well as considerable resources, scientists and engineers at Evalve, collaborating with physicians, worked to solve this unmet medical need from the 1990s when Evalve was founded, through the late 2000s and early 2010s when the product of their efforts ultimately received marketing approval (first in Europe and later in the U.S.). These efforts resulted in the MitraClip.

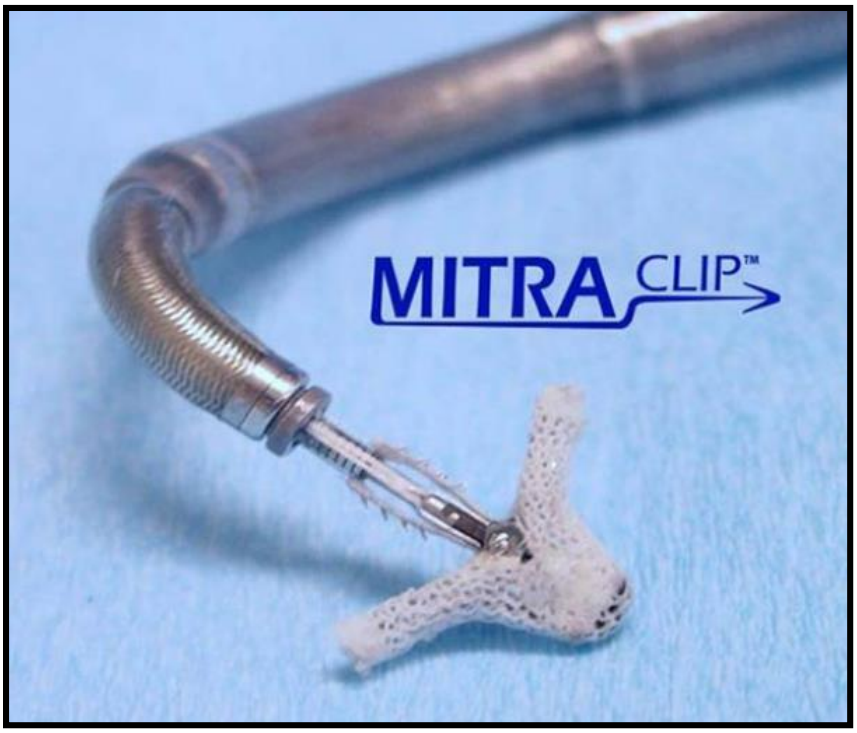

Figure 4
(https://www.ctsnet.org/article/brief-description-percutaneous-mitral-repair-procedure-using-mitraclip%C2%AE-device)

47. After conceiving of this innovative technology, the Evalve team conducted feasibility studies with the new device in the laboratory and in animals, demonstrating that it could successfully resolve MR without open-heart surgery.

48. Based on this data, in 2003, the U.S. Food and Drug Administration ("FDA") approved the conduct of trials in humans, allowing Evalve's collaboration with the medical community in the development of an entirely new medical procedure with tremendous benefits for patients.

49. In July 2003, Evalve commenced clinical trials to evaluate the safety and effectiveness of the MitraClip, including the Endovascular Valve Edge-to-Edge Repair Study ("EVEREST") I, EVEREST II Randomized Clinical Trial, and the EVEREST II High Risk Registry Study. These trials provided additional information and data regarding the safety and efficacy of the MitraClip.

50. Based on these clinical trials, the MitraClip device received regulatory approval from agencies around the world. The MitraClip device received "CE-Mark" approval for marketing in Europe in 2008, and is now approved for commercial distribution in over two-dozen European countries.

51. The MitraClip also received FDA approval for marketing in the United States in 2013.

Abbott's Continued Investment In MitraClip

52. Recognizing the value of the technology Evalve had developed, Abbott Laboratories fully acquired Evalve in 2009, increasing the stake it had previously held following the 2006 acquisition of the vascular device division of Guidant Corporation.

53. Abbott has since devoted significant resources to the further development and production of the MitraClip device.

54. Abbott has trained and deployed a global workforce to develop clinical training and sales channels and relationships with MitraClip customers, including medical facilities and physicians. Abbott also has devoted significant resources to educating the medical community about edge-to-edge transcatheter mitral valve repair and its benefits.

55. Abbott also has devoted, and continues to devote, considerable resources to the MitraClip's clinical development. For example, after the MitraClip received regulatory approval, Abbott sponsored the ACCESS-EU trial in Europe, and the REALISM trial in the United States, to further assess the safety and efficacy of the MitraClip.

56. More recently, Abbott conducted the COAPT trial to further study MitraClip in symptomatic secondary (functional) MR patients. The results of this study—unveiled at the Transcatheter Therapeutics (TCT) conference in San Diego in September 2018—showed that MitraClip treatment "significantly reduced not only the primary endpoint of heart failure (HF) rehospitalizations, but also mortality at 2 years."[14]

57. Abbott also has invested significantly in further development of the MitraClip, in response to physician feedback. Abbott has developed next-generation versions of the MitraClip that build upon Evalve's successful work, to further improve the MitraClip features and ease-of-use and treatment of a broader range of patients.

[14] *See* Shelley Wood, *COAPT: MitraClip Reduced Repeat Hospitalizations, Mortality in Functional MR Patients With Severe HF*, TCTMD, https://www.tctmd.com/news/coapt-mitraclip-reduces-repeat-hospitalizations-mortality-functional-mr-patients-severe-hf (last visited: March 4, 2019).

58. Abbott's development efforts resulted in the second-generation MitraClip NT, which received CE-Mark approval in December 2015 and FDA approval in 2016, and the third generation MitraClip NTR and XTR, which received CE-Mark approval for use in Europe in early 2018 and FDA approval in June 2018.

59. Abbott also continues to work on further enhancements to the MitraClip and plans to launch subsequent generations of MitraClip over the next several years.

Features of the MitraClip

60. As shown in the images below, the MitraClip treats MR by grasping the mitral valve leaflets from the atrial and ventricular sides and bringing them closer to perform an edge-to-edge repair without the trauma of open-heart surgery. This closer arrangement of the leaflets allows more effective closing of the valve to reduce or eliminate undesirable reverse flow, or MR.

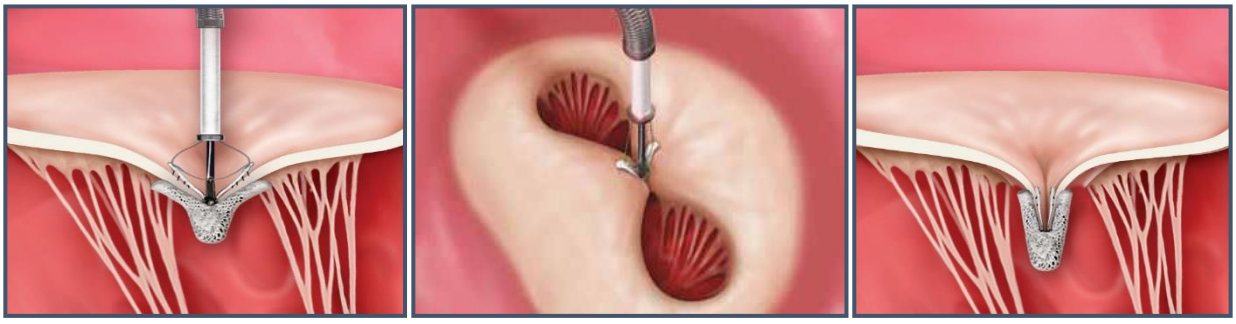

Figure 5
(https://www.heartvascularcentre.com/treatments/)

61. The MitraClip is delivered to a beating heart through a minimally invasive procedure that uses a catheter introduced through the patient's femoral vein. A physician can navigate the MitraClip through the patient's vasculature to the site of the MR in the heart, and then advance and manipulate the MitraClip for proper positioning and permanent placement on the mitral valve remotely from outside the patient's body.

62. The minimally invasive nature of the MitraClip obviates the need for open-heart surgery.

The Success of MitraClip

63. MitraClip is the only approved transcatheter option for edge-to-edge mitral valve repair, and it delivers meaningful improvement in cardiac function with a low safety risk and low incidence of device complications.

64. MitraClip has received extensive industry and clinical praise and recognition for its contributions to cardiovascular care.

65. As just a few of many examples, physicians have praised MitraClip as a "first-in-class transcatheter mitral valve repair device."[15]

66. Others have said "[i]t is clear that the MitraClip offers significant clinical and quality-of-life benefit to patients, with an excellent safety profile compared with surgical intervention."[16]

67. MitraClip has been recognized as "the predominant alternative non-surgical treatment option for patients with symptomatic mitral regurgitation (MR) who were judged inoperable by a heart team …demonstrating a wide acceptance for this interventional treatment."[17]

[15] Eric J. Velazquez, et al., *The MitraClip and Survival in Patients with Mitral Regurgitation at High Risk for Surgery: A Propensity-matched Comparison*, AM. HEART J., VOL. 170, No. 5, pp. 1050-1059 at 1050 (2015).

[16] Alice Perlowski & Ted Feldman, *Percutaneous Treatment of Mitral Regurgitation: The MitraClip Experience*, INTERVENT CARDIOL. CLIN., Vol. 1 pp. 63-72 at 71 (2012).

[17] Martin Orban & Jörg Hausleiter, *Edge-to-Edge Mitral Valve Repair: Solid Data and a Prosperous Future*, HEART 104(4):280-281 at 280 (2018).

68. Others have credited MitraClip for "significantly advanc[ing] the field of transcatheter therapy for mitral valve regurgitation [and] … becom[ing] the most widely adopted TMVR [*sic*] approach worldwide …."[18]

69. As described in a front-page article in the New York Times, after seeing the results of the COAPT study, physicians have called MitraClip a "game changer" and "a huge advance," and commented that it "will change how we treat these patients."[19]

70. Abbott has received a number of industry awards for the MitraClip.

71. In 2017, Fast Company named Abbott to its annual list of the top 10 most innovative companies and emphasized the MitraClip as one of Abbott's "Latest Breakthroughs."

72. In 2015, Abbott won the Chicago Innovation Award for the MitraClip.

73. The MitraClip also won the gold in the 2011 Edison Awards as the best new surgical aid product in the science and medical category.

74. And in 2010, the MitraClip received the DiNA award for Outstanding Therapeutic and Product medical device.

75. In addition to this industry praise and recognition, the USPTO, as well as other patent offices around the world, have awarded patents on the technology that is essential to clipping devices and embodied by the MitraClip, including the Patents-in-Suit.

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[18] Mario Gössl, et al., *Current Status of Catheter-Based Treatment of Mitral Valve Regurgitation*, CURR. CARDIOL. REP. 19:38 at 1-2 (2017).

[19] *See* Gina Kolata, *Tiny Device is a 'Huge Advance' for Treatment of Serious Heart Failure*, THE NEW YORK TIMES (Sept. 23, 2018), *available at:* https://www.nytimes.com/2018/09/23/health/heart-failure-valve-repair-microclip.html (last visited: March 4, 2019).

Edwards' Failed Attempt At Transcatheter Edge-to-Edge Mitral Valve Repair

76. Edwards attempted to develop and market an edge-to-edge transcatheter mitral valve repair system, but was not successful.

77. Specifically, Edwards failed with its "Mobius" Leaflet Repair System that it attempted to develop in the 2000s. The Mobius system attempted to repair the mitral valve using a catheter-delivered "stitch" to effect an edge-to-edge mitral valve repair.

78. Edwards tried to develop this "Mobius" device into a viable commercial product for eight years. However, the investigation and development of the Mobius device was suspended because of "mixed results, procedural complexity, and a perceived limited patient population."[20]

79. The poor durability and low procedural success rate of Mobius led investigators to suspend further experimentation with the device during phase 1 of clinical trials.[21]

80. At the 30-day follow-up period, less than one-half of the total patients enrolled had a successful stitch in place.[22]

81. Edwards ultimately discontinued the Mobius system, and never brought it to market.

[20] Michael J. Mack, *Percutaneous treatment of mitral regurgitation: So near, yet so far!*, J. of THORACIC AND CARDIOVASCULAR SURGERY 135(3):238 at 238 (2008).

[21] Nocolo Piazza, et al., *Transcatheter Mitral and Pulmonary Valve Therapy*, J. AM. COLLEGE OF CARDIOLOGY. 53(20):1837-1851 at 1840 (2009).

[22] *Id.*

82. Subsequently, in 2012, Edwards' CEO acknowledged that "[t]he minimally invasive transcatheter route for mitral valve repair 'has been a tough one' for the company to break into."[23]

Edwards' Development of the Infringing PASCAL Device

83. Edwards did not stop its efforts to bring to market an edge-to-edge transcatheter mitral valve repair system after its failure with the Mobius system. Rather, Edwards saw the success of Abbott's patent-protected MitraClip device and set out to copy Abbott's patented technology. The result is PASCAL: Edwards' infringing mitral valve repair system.

84. PASCAL is described in slides from a September 2018 presentation by Ted Feldman, M.D., at the PCR London Valves Conference[24]:

[23] *Edwards' pursuit of transcatheter mitral valve repair options continues, CEO says*, THE GRAY SHEET 12(70), Elsevier, Inc. (July 2, 2012).

[24] Ted Feldman, *Case-based learning for the Heart Valve Team: percutaneous treatment of primary MR -- Device options: leaflet repair*, 2018 PCR LONDON VALVES PRESENTATION (Sept. 9-11, 2018) *available at:* https://media.pcronline.com/diapos/PCRLondon2018/11-20180910_1130_Room_3_Feldman_Ted_1111_(975)/Feldman_Ted_20181009_1130_Room_3.pdf (last visited: March 4, 2019).

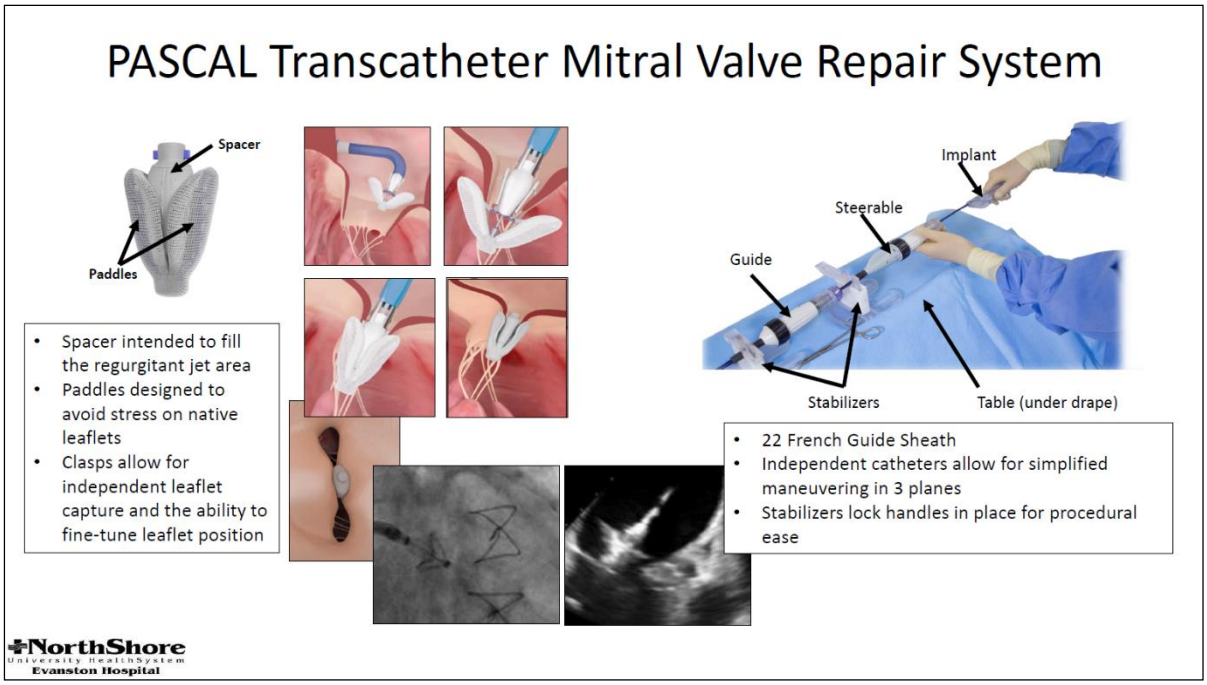

Figure 6

85. Edwards also published results from a PASCAL feasibility study in mid-2017 in *The Lancet*.[25]

86. Edwards also has published information about PASCAL, including an animation of the PASCAL procedure, on its website. [26]

87. On February 19, 2019, Edwards announced that it had received CE-Mark approval to commercially market PASCAL in Europe.[27] Since receiving CE-Mark approval, Edwards has commenced commercial sales of PASCAL in Europe.

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[25] *See* Fabien Praz, et al., *Compassionate use of the PASCAL transcatheter mitral valve repair system for patients with severe mitral regurgitation: a multicenter, prospective, observational, first-in-man study*, THE LANCET 390:773-80 at 779 (2017).

[26] https://www.edwards.com/gb/devices/transcatheter-valve-repair/PASCAL (last visited March 4, 2019).

[27] https://www.edwards.com/ns20190219 (last visited March 4, 2019).

88. Edwards manufactures, has manufactured, and will manufacture PASCAL in the United States for export, use, sale, and offer for sale outside the United States, including Europe, without authorization from Abbott.

Edwards' Infringement Has and Will Irreparably Harm Abbott

89. Edwards' infringing manufacture of PASCAL is irreparably harming, and will continue to irreparable harm, Abbott by artificially creating a two-player market, with Abbott having to compete against its own patented technology.

90. Abbott has invested years and hundreds of millions of dollars in acquiring Evalve and developing MitraClip. To obtain regulatory approval, Abbott had to convince regulatory bodies that MitraClip is a safe and effective treatment—a particularly challenging effort for what the FDA called "a first-in-class device representing a breakthrough technology."[28] Abbott also had to build the market for its device from scratch by educating and training physicians in this brand new technique for mitral valve repair, and securing reimbursement for patients for the MitraClip procedure.

91. Through its infringing PASCAL device, Edwards is unjustly and irreparably reaping the benefits of Abbotts's investments, without contributing to them. PASCAL uses MitraClip's patented features and is designed to take away MitraClip customers. Edwards told investors that PASCAL's "going to be a[n] … alternative for a market ….with … only one

[28] Letter from Denise Hinton, Chief Scientist, FDA to Stephanie Philbin, Goodwin & Proctor LLP, Re: Citizen Petition for Due Diligence Determination of Patent Term Extension for MITRACLIP CDS; Docket Nos. FDA-2014-E-2358; FDA-2014-E-2359 (FDA RADM Chief Scientist Letter) at 7–8 (July 12, 2018) (denying petition).

competitor," MitraClip, and serve "a patient population that's already being served" by MitraClip.[29]

92. Abbott also has been harmed by having to divert resources to respond to PASCAL's unlawful infringement.

93. Edwards already is using MitraClip's success in Abbott's COAPT clinical trial to propel PASCAL, telling investors that ***Abbott's*** "COAPT" trial "showed that ***we*** can alter the natural history of mitral regurgitation and … reduce mortality by intervening."[30] Edwards also pointed to the "built-in market that's already been developed over time" by Abbott, the "tailwind" for PASCAL that MitraClip's results created, and the fact that "there's already reimbursement and approval process [] in place."[31]

94. Abbott's harm from Edwards' infringement by the launch of PASCAL is and will be irreparable and unquantifiable, and it cannot be made whole by damages alone.

Edwards' Infringement Is Willful

95. Edwards has commercially manufactured the infringing PASCAL product in the U.S., and launched and continued to sell its infringing PASCAL product in Europe, despite having knowledge of the Patents-in-Suit and PASCAL's infringement.

[29] Transcript, Edwards Lifesciences Corp at Canaccord Genuity Growth Conference at 5-6 (Aug. 9, 2017); Transcript, Edwards Lifesciences Corporation Presentation at Goldman Sachs 39th Annual Global Healthcare Conference at 13 (June 13, 2018).

[30] Transcript, Edwards Lifesciences Corporation Analyst/Investor Day at 30 (Dec. 5, 2018).

[31] Transcript, Edwards Lifesciences Corporation Presentation at Goldman Sachs 39th Annual Global Healthcare Conference at 33 (June 13, 2018); Transcript, Edwards Lifesciences Corporation Analyst/Investor Day at 12 (Dec. 5, 2018); Transcript, Edwards Lifesciences Corporation at Wells Fargo Securities Healthcare Conference at 8 (Sep. 6, 2018).

96. MitraClip has been clearly marked for years with the numbers of each of the '097, '813, '267, and '388 patents, and Edwards studied MitraClip to develop PASCAL. Edwards intended PASCAL to compete against MitraClip in MitraClip's "built-in market." To seek regulatory approval, Edwards is testing PASCAL against MitraClip in a "noninferiority" study.

97. Edwards listed each of the five Patents-in-Suit on a May 24, 2018 Information Disclosure Statement submitted during prosecution of U.S. Patent Application No. 15/909,803.

98. Edwards is also aware of Abbott's initial Complaint in this action, filed on January 28, 2019, and Abbott's Motion for a Preliminary Injunction, and supporting declarations and exhibits, filed on January 29, 2019. Those filings informed Edwards in detail about the reasons PASCAL infringes the Patents-In-Suit and the harm PASCAL causes Abbott.

99. In response to Abbott's Motion for a Temporary Restraining Order, Edwards raised meritless non-infringement theories and no arguments whatsoever that any Patents-In-Suit were invalid.

100. Edwards is also aware that the Court issued an Order on March 5, 2019 stating that "it appears that Abbott may be able to establish a case on the merits" of its patent infringement claims.[32]

101. Despite its knowledge of the Patents-in-Suit, Abbott's infringement contentions, the Court's Order, and the harm PASCAL causes, and despite having no viable defense to infringement, Edwards has proceeded to infringingly manufacture PASCAL in the U.S. and to export and sell its infringingly manufactured PASCAL in Europe.

[32] D.I. 63 at 3.

102. Edwards has also indicated that it intends to continue to sell PASCAL even if this Court determines that PASCAL's manufacture likely infringes and causes Abbott irreparable harm.

103. Edwards' knowing infringement of the Patents-in-Suit has been, is, and will be willful, wanton and egregious.

THE PATENTS-IN-SUIT

104. Abbott has invested heavily in developing and maintaining a portfolio of patents covering the MitraClip, including the Patents-in-Suit.

105. The '097 patent is titled "Surgical device for connecting soft tissue," and was duly and legally issued on October 30, 2007.

106. A true and correct copy of the '097 patent is attached as **Exhibit A**.

107. On February 26, 2019, the USPTO issued a Notice of Final Determination stating that "[a] determination has been made that U.S. Patent No. 7,288,097, which claims the medical device, the MitraClip CDS, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,759 days."[33] The Notice further states that the "Expiration Date of Extension" is "October 7, 2023."[34]

108. The '813 patent is titled "Methods and devices for capturing and fixing leaflets in valve repair," and was duly and legally issued on June 22, 2004.

109. A true and correct copy of the '813 patent is attached as **Exhibit B**.

[33] Notice of Final Determination of Patent Term Extension for U.S. Patent No. 7,288,097 (February 26, 2019).

[34] *Id.*

110. The ’267 patent is titled “Fixation device and methods for engaging tissue,” and was duly and legally issued on July 21, 2009.

111. A true and correct copy of the ’267 patent is attached as **Exhibit C**.

112. The ’388 patent is titled “Fixation devices, systems and methods for engaging tissue,” and was duly and legally issued on June 15, 2010.

113. A true and correct copy of the ’388 patent is attached as **Exhibit D**.

114. The ’493 patent is titled “Fixation devices, systems and methods for engaging tissue,” and was duly and legally issued on November 15, 2011.

115. A true and correct copy of the ’493 patent is attached as **Exhibit E**.

EDWARDS’ WILLFUL INFRINGEMENT OF THE ASSERTED PATENTS

116. Abbott repeats and re-alleges the allegations of paragraphs 1 through 115 above.

117. As shown in the claim chart in **Exhibit F**, Edwards’ PASCAL device meets each and every limitation of at least claim 1 of the ’097 patent, either literally and/or under the doctrine of equivalents. Thus, Edwards’ manufacture of PASCAL in the United States, including for export, use, sale and offer for sale outside of the United States, infringes at least claim 1 of the ’097 patent under 35 U.S.C. § 271(a). Edwards’ infringement of the ’097 patent has been willful, wanton and egregious.

118. As shown in the claim chart in **Exhibit G**, Edwards’ PASCAL device meets each and every limitation of at least claim 113 of the ’813 patent, either literally and/or under the doctrine of equivalents. Thus, Edwards’ manufacture of PASCAL in the United States, including for export, use, sale and offer for sale outside of the United States, infringes at least claim 113 of the ’813 patent under 35 U.S.C. § 271(a). Edwards’ infringement of the ’813 patent has been willful, wanton and egregious.

119. As shown in the claim chart in **Exhibit H**, Edwards' PASCAL device meets each and every limitation of at least claim 1 of the '267 patent, either literally and/or under the doctrine of equivalents. Thus, Edwards' manufacture of PASCAL in the United States, including for export, use, sale and offer for sale outside of the United States, infringes at least claim 1 of the '267 patent under 35 U.S.C. § 271(a). Edwards' infringement of the '267 patent has been willful, wanton and egregious.

120. As shown in the claim chart in **Exhibit I**, Edwards' PASCAL device meets each and every limitation of at least claim 1 of the '388 patent, either literally and/or under the doctrine of equivalents. Thus, Edwards' manufacture of PASCAL in the United States, including for export, use, sale and offer for sale outside of the United States, infringes at least claim 1 of the '388 patent under 35 U.S.C. § 271(a). Edwards' infringement of the '388 patent has been willful, wanton and egregious.

121. As shown in the claim chart in **Exhibit J**, Edwards' PASCAL device meets each and every limitation of at least claim 1 of the '493 patent, either literally and/or under the doctrine of equivalents. Thus, Edwards' manufacture of PASCAL in the United States, including for export, use, sale and offer for sale outside of the United States, infringes at least claim 1 of the '493 patent under 35 U.S.C. § 271(a). Edwards' infringement of the '493 patent has been willful, wanton and egregious.

122. Thus, Edwards' manufacture of PASCAL in the United States, including for export, use, sale and offer for sale outside of the United States, willfully infringes at least one claim of each of the Patents-in-Suit at least pursuant to 35 U.S.C. § 271(a).

FIRST CAUSE OF ACTION

(Infringement of the ’097 Patent)

123. Abbott repeats and re-alleges the allegations of paragraphs 1 through 122 above.

124. Edwards has infringed, and is infringing, one or more claims of the ’097 patent through its manufacture of PASCAL in the United States, including for export, use, sale and offer for sale outside of the United States. Edwards is liable for infringement at least pursuant to 35 U.S.C. § 271(a).

125. Unless enjoined by this Court, Edwards will continue to infringe the ’097 patent and as a direct result Abbott will continue to suffer harm, including irreparable harm for which there is no adequate remedy at law. Accordingly, Abbott is entitled to preliminary and permanent injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

126. Abbott will suffer damage as a direct and proximate result of Edwards’ infringement of the ’097 patent. Thus, in addition to injunctive relief, Abbott is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

127. Edwards’ infringement of the ’097 patent has been willful, wanton and egregious. Abbott is thus also entitled to enhanced damages up to three times the amount of assessed damages under 35 U.S.C. § 284.

SECOND CAUSE OF ACTION

(Infringement of the ’813 Patent)

128. Abbott repeats and re-alleges the allegations of paragraphs 1 through 126 above.

129. Edwards has infringed, and is infringing, one or more claims of the ’813 patent through its manufacture of PASCAL in the United States, including for export, use, sale and offer

for sale outside of the United States. Edwards is liable for infringement at least pursuant to 35 U.S.C. § 271(a).

130. Unless enjoined by this Court, Edwards will continue to infringe the '813 patent and as a direct result Abbott will continue to suffer harm, including irreparable harm for which there is no adequate remedy at law. Accordingly, Abbott is entitled to preliminary and permanent injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

131. Abbott will suffer damage as a direct and proximate result of Edwards' infringement of the '813 patent. Thus, in addition to injunctive relief, Abbott is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

132. Edwards' infringement of the '813 patent has been willful, wanton and egregious. Abbott is thus also entitled to enhanced damages up to three times the amount of assessed damages under 35 U.S.C. § 284.

THIRD CAUSE OF ACTION

(Infringement of the '267 Patent)

133. Abbott repeats and re-alleges the allegations of paragraphs 1 through 131 above.

134. Edwards has infringed, and is infringing, one or more claims of the '267 patent through its manufacture of PASCAL in the United States, including for export, use, sale and offer for sale outside of the United States. Edwards is liable for infringement at least pursuant to 35 U.S.C. § 271(a).

135. Unless enjoined by this Court, Edwards will continue to infringe the '267 patent and as a direct result Abbott will continue to suffer harm, including irreparable harm for which there is no adequate remedy at law. Accordingly, Abbott is entitled to preliminary and permanent injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

136. Abbott will suffer damage as a direct and proximate result of Edwards' willful infringement of the '267 patent. Thus, in addition to injunctive relief, Abbott is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

137. Edwards' infringement of the '267 patent has been willful, wanton and egregious. Abbott is thus also entitled to enhanced damages up to three times the amount of assessed damages under 35 U.S.C. § 284.

FOURTH CAUSE OF ACTION

(Infringement of the '388 Patent)

138. Abbott repeats and re-alleges the allegations of paragraphs 1 through 136 above.

139. Edwards has infringed, and is infringing, one or more claims of the '388 patent through its manufacture of PASCAL in the United States, including for export, use, sale and offer for sale outside of the United States. Edwards is liable for infringement at least pursuant to 35 U.S.C. § 271(a).

140. Unless enjoined by this Court, Edwards will continue to infringe the '388 patent and as a direct result Abbott will continue to suffer harm, including irreparable harm for which there is no adequate remedy at law. Accordingly, Abbott is entitled to preliminary and permanent injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

141. Abbott will suffer damage as a direct and proximate result of Edwards' infringement of the '388 patent. Thus, in addition to injunctive relief, Abbott is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

142. Edwards' infringement of the '388 patent has been willful, wanton and egregious. Abbott is thus also entitled to enhanced damages up to three times the amount of assessed damages under 35 U.S.C. § 284.

FIFTH CAUSE OF ACTION

(Infringement of the ’493 Patent)

143. Abbott repeats and re-alleges the allegations of paragraphs 1 through 141 above.

144. Edwards has infringed, and is infringing, one or more claims of the ’493 patent through its manufacture of PASCAL in the United States, including for export, use, sale and offer for sale outside of the United States. Edwards is liable for infringement at least pursuant to 35 U.S.C. § 271(a).

145. Unless enjoined by this Court, Edwards will continue to infringe the ’493 patent and as a direct result Abbott will continue to suffer harm, including irreparable harm for which there is no adequate remedy at law. Accordingly, Abbott is entitled to preliminary and permanent injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

146. Abbott will suffer damage as a direct and proximate result of Edwards’ infringement of the ’493 patent. Thus, in addition to injunctive relief, Abbott is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

147. Edwards’ infringement of the ’493 patent has been willful, wanton and egregious. Abbott is thus also entitled to enhanced damages up to three times the amount of assessed damages under 35 U.S.C. § 284.

PRAYER FOR RELIEF

WHEREFORE, Abbott prays for the following relief:

(a) A judgment that Edwards has infringed and is infringing each of the Patents-in-Suit;

(b) An order preliminarily and permanently enjoining Edwards, its officers, agents, servants, employees and attorneys, all parent, subsidiary, and affiliate corporations and other

related business entities, and all other persons or entities acting in concert, participation or in privity with one or more of them, and their successors and assigns, from infringing, contributing to the infringement of, or inducing others to infringe the Patents-in-Suit;

(c) A judgment awarding Abbott damages, in an amount to be determined at trial, together with interest and costs as fixed by the Court;

(d) A judgment awarding Abbott enhanced damages, up to three times the amount of damages found or assessed;

(e) A judgment that this is an exceptional case, and awarding Abbott reasonable attorneys' fees and its costs and reimbursements in this action, as provided by 35 U.S.C. § 285;

(f) A judgment and order awarding Abbott an accounting and/or supplemental damages for all damages occurring after any discovery cutoff and through the Court's decision regarding the imposition of a permanent injunction;

(g) Any and all other and further relief as the Court deems just and proper.

JURY DEMAND

Abbott demands a trial by jury on all issues so triable in this Complaint.

/s/ David M. Fry

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